ASX Announcement

8 June 2023

First Patient Dosed in ATL1102 Phase IIb Duchenne Muscular Dystrophy (DMD) Trial

Key Highlights:

- First patient with DMD received ATL1102 or Placebo, in Turkey, on 6 June 2023.
- 3 patients currently in screening phase of the trial.
- Trial to recruit 45 male patients aged 10 to <18 years across at least 12 clinical sites in 4 countries.
- Results from the initial 24-week treatment period anticipated mid-2024.

Antisense Therapeutics Limited [ASX:ANP | US OTC:ATHJY | FSE:AWY] (ANP or Company) is pleased to announce a significant milestone in the development of ATL1102 for Duchenne muscular dystrophy. Recruitment has commenced in the multicentre double-blind, placebo-controlled Phase IIb trial of ATL1102 in non-ambulant boys with DMD and the first participant has been randomised and dosed with ATL1102 or Placebo in Turkey. This first patient was enrolled by Professor Haluk Topaloglu MD, Yeditepe University Kosuyolo Hospital Istanbul, Turkey.

"This is a major milestone for Antisense Therapeutics and the DMD community", said Dr Charmaine Gittleson, Antisense Board Chair. "I am excited that ATL1102 has again entered a clinical trial and we genuinely hope the study participants and future patients with DMD will benefit from this treatment."

The Phase IIb trial, led by Coordinating Principal Investigator Professor Thomas Voit MD, University College London United Kingdom (UK), will evaluate the effect of ATL1102 on upper limb muscle function in non-ambulant participants with DMD, as assessed by (i) difference in the Performance of Upper Limb Module for DMD 2.0 (PUL 2.0) score against placebo at 6 months; (ii) stabilisation or improvement of clinical effect after 12 months of treatment; and (iii) the clinical impact of delayed treatment between the placebo and active treatment groups.

The trial is a two-part design to evaluate the efficacy, safety, pharmacokinetics and pharmacodynamics of ATL1102. Participants will be enrolled and randomised to receive either ATL1102 (25mg dose), ATL1102 (50mg dose) or matched placebo in a 1:1:1 ratio given as a weekly subcutaneous injection for a 24-week randomized, double-blind, placebo-controlled treatment period (Part A). Efficacy and safety data will be assessed at the end of Part A. Participants will then continue to the Open Label Extension treatment period (Part B) and continue to receive ATL1102 (25mg or 50mg dose) for a further 24 weeks. Participants on placebo in Part A will cross over to receive ATL1102 in Part B. A four month follow up period occurs after Part B. Further trial details will shortly be available for public view on clinicaltrials.gov.

Professor Voit noted "I am very pleased that the ATL1102 Phase IIb clinical trial has commenced patient enrolment. There is high need for new therapeutic approaches for the treatment of DMD and this trial is an important step towards finding effective treatment options for DMD patients and providing hope for their families."

The trial will be conducted across at least 12 clinical sites located in Australia, Bulgaria, United Kingdom and Turkey. Presently Turkey and Bulgaria have regulatory approvals with Turkish sites actively screening potential participants. Site activation in Bulgaria is imminent. In Australia, ethics approval has been granted and the Clinical Trial Notification submitted to the Therapeutic Goods Administration and we are currently awaiting final institutional (hospital) approval. Approval from the MHRA in the UK is anticipated within the coming weeks. Once all countries and sites are open the Company looks forward to recruitment accelerating accordingly.

As we progress through the trial, we look forward to sharing investor updates on significant developments as they become available.

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This announcement has been authorised for release by the Board.

About Antisense Therapeutics Limited [ASX: ANP | US OTC: ATHJY | FSE: AWY] is a publicly listed biotechnology company developing and commercializing antisense pharmaceuticals for rare diseases with significant unmet medical need. The company's lead program is ATL1102, an antisense inhibitor of the CD49d receptor, which is currently the subject of an ongoing international Phase IIb trial for Duchenne Muscular Dystrophy. The drug previously reported highly promising results from an exploratory Phase II trial.